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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,067	07/03/2003	David Lewis	239770US0DIV	3508

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EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,067	LEWIS ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/21/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 24, 28-36, 39-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Ashurst et al (6,131,566).

Ashurst et al teach a metered dose inhaler having all or part of its internal surfaces coated with one or more fluorocarbon polymers, for dispensing an inhalation drug formulation comprising active agents, a propellant and optionally in combination with excipients (see abstract and summary). The metered dose inhalers typically comprise a canister and a valve (col. 1, lines 27-40, col. 4, lines 32-53 and col. 6, lines 45-51). Exipients include co-solvents such as ethanol and antioxidants (see col. 2, lines

62-65). Ashurst discloses that a polar cosolvent such as ethanol may be included in the drug formulation, typically in the amount of 0.1 to 5% by weight (col. 3, lines 11-18). The formulation may contain albuterol in combination with one or more other active agents such as beclomethasone dipropionate, flunisolide, etc (col. 3, lines 19-40). Suitable propellants include HFAs such as p134a and p227 (see col. 4, lines 1-6). The said formulations administered by the said MDIs are suitable for treating respiratory disorders such as asthma (col. 6, lines 64-67).

Claims 24, 28-36, 39-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Cutie (5,891,419).

Cutie teaches aerosol formulations for mucosal and/or topical administration containing one or more drugs and a sugar as a dispersant in a pharmaceutically acceptable propellant. Metered dose inhalers suitable for delivering such formulations are also disclosed. Cutie discloses that in an aerosol drug formulation the drug may be dissolved in the propellant (col. 1, lines 24-29). In a solution formulation, a cosolvent may be added to enhance drug dissolution (col. 2, lines 3-10). The formulations may contain ethanol up to 5% of the formulation (col. 5, lines 5-9). Drugs which may be administered via the said formulations include flunisolide, beclomethasone, triamcinolone, budesonide (col. 4, lines 25-35). The said formulations may contain excipients such as antioxidants (col. 5, lines 31-34). The formulations may be filled into conventional aerosol containers using conventional filling equipment well known to those skilled in the art (col. 5, lines 40-45). Examples such as example 5, 7, 8 and 11

show formulations comprising an active agent such as triamcinolone or flunisolide, ethanol and propellant.

Claims 24, 28-36, 39-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Tzou et al (5,776,433).

Tzou teaches flunisolide aerosol formulations comprising a therapeutically effective amount of flunisolide in solution with ethanol and a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane and a mixture thereof used for the treatment of bronchial asthma. The formulations may be delivered by a metered dose inhaler with a canister that is inert to flunisolide (see abstract). Tzou discloses that NASALIDE® nasal solution comprises excipients such as butylated hydroxyanisole (col. 1, lines 17-26). It is also disclosed that in the formulations of the invention, the flunisolide is fully dissolved and the formulation is free from undissolved flunisolide (col. 2, lines 36-40). Aerosol canisters equipped with conventional valves, preferably metered dose valves (col. 3, lines 45-50).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25-27, 37-38, 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashurst et al (6,131,566) in view of Rubin (4,584,320).

Ashurst et al, discussed above, while disclosing the addition of antioxidants to the inhalation formulations, lacks disclosure on specific antioxidants.

Rubin teaches anti-asthmatic compositions for oral or nasal administration. The said formulations comprise an active agent, a suitable propellant and excipients. Since

the active agents are subject to oxidation, antioxidants should be added. Suitable antioxidants include butylated hydroxytoluene, butylated hydroxyanisole, ascorbic acid, ascorbyl palmitate, tocopherol etc (col. 3, lines 38-53 and claim 6).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general formulations of Ashurst to have looked in the art for specific antioxidants suitable for inhalation preparations such as tocopherol and ascorbyl palmitate, with the reasonable expectations of successfully preparing a stable and efficient formulation for treating respiratory disorders.

Claims 25-27, 37-38, 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cutie (5,891,419) in view of Rubin (4,584,320).

Cutie, discussed above, lacks disclosure on specific antioxidants.

Rubin teaches anti-asthmatic compositions for oral or nasal administration. The said formulations comprise an active agent, a suitable propellant and excipients. Since the active agents are subject to oxidation, antioxidants should be added. Suitable antioxidants include butylated hydroxytoluene, butylated hydroxyanisole, ascorbic acid, ascorbyl palmitate, tocopherol etc (col. 3, lines 38-53 and claim 6).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general formulations of Cutie on solution formulations of

corticosteroids for inhalation and treatment of respiratory disorders to have looked in the art for specific antioxidants that would improve stability and efficiency of the inhaled formulations as taught by Rubin.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,713,047 in view of Rubin (4,584,320). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant Application and the claims of the U.S. Patent are essentially drawn to the same formulations, inhalers and method of treating. The difference is that the instant claims require addition of an

antioxidant. Rubin teaches addition of an antioxidant to formulations that are subject to oxidation. Thus it would have been obvious to one of ordinary skill in the art to have implemented the teachings of Rubin and have added the antioxidants in the said formulations of the instant application.

Claims 24-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-14, 16-26, 28-32, 48-49 of copending Application No. 10/612,072 (US 20040096399). Although the conflicting claims are not identical, they are not patentably distinct from each other because both Applications contain claims drawn to an aerosol formulation comprising a corticosteroid, a propellant, a cosolvent and an antioxidant. Both Applications also have claims drawn to a pressurized metered dose inhaler comprising the said formulation and a method of treating respiratory disorders by administration of the said formulation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 24-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application Nos. 10/275,891 (US 20030190289); 10/435,032 (US 20030206870); 10/435,354 (US 20030190287); 10/766,857 (US 20040184993) in view of Rubin (4,584,320). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant Application and the claims of the co-pending Applications are essentially drawn to the same formulations, inhalers

and method of treating. The difference is that the instant claims require addition of an antioxidant. Rubin teaches addition of an antioxidant to formulations that are subject to oxidation. Thus it would have been obvious to one of ordinary skill in the art to have implemented the teachings of Rubin and have added the antioxidants in the said formulations of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Interference

Applicant had submitted a request for an interference with U.S. Patent Application No. 10/176,851 (Published as US 20030053957) naming Buenafae et al as inventors.

Applicant is notified herewith that the named Application has been Abandoned, thus the request for interference is dismissed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SABIHA QAZI, PH.D
PRIMARY EXAMINER

Mina Haghighatian
August 17, 2006